K062215

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510(K) SUMMARY

In accordance with 21 CFR 807.92, the following information constitutes Confidant's summary for the Confidant 2.0 System.

SUBMITTER'S NAME:	Confidant Inc.
ADDRESS:	2530 Meridian Parkway, Suite 300
CONTACT PERSON:	Daniel R. Plonski
CONTACT PERSON TITLE	Director of Product Management
TELEPHONE NUMBER:	(919) 806-4323
FAX NUMBER:	(919) 806-4802
DATE OF SUBMISSION:	July 27, 2006

1 Identification of device

Proprietary Name: Confidant 2.0

Common Name: Physiological Transmitter and Receiver

Classification Status: Class II per regulations 870.2910

Product Codes: DRG

2 Equivalent devices

Confidant Inc. believes that Confidant 2.0 is substantially equivalent to the following legally marketed device:

- The Hermes System K050929 (DRG)

3 Description of the device

Confidant 2.0 is an accessory device that collects data from a range of supported measurement devices. The data is collected and sent using standard wireless technologies and maintained on an associated database server located within the healthcare facility. Based on patient specific parameters set by the healthcare provider, educational and motivational messages are returned to the patient. Confidant 2.0 currently supports several models of glucose meters, non-invasive blood pressure cuffs and weight scales.

Confidant 2.0 messages remind the user of good health habits such as taking all prescribed measurements and maintaining a healthy lifestyle. Confidant 2.0 can send email to the patient's doctor and/or guardian if good habits are not maintained.

4 *Intended use*

Confidant 2.0 is intended to be used by out-of-hospital patients as a means to collect and transmit medical measurements (such as blood glucose level, weight, and blood pressure) to their healthcare provider and to receive returned educational and motivational messages to help them better understand and manage their chronic condition. Confidant 2.0 is to be used only upon prescription of a licensed physician or other authorized healthcare provider.

Confidant 2.0 is not intended for emergency calls or for transmission or indication of any real-time alarms or time-critical data. This device is not intended as a substitute for direct medical supervision or emergency intervention.

Confidant 2.0 is not intended to provide automated treatment decisions, or to be used as a substitute for professional healthcare judgment. All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

5 *Technological characteristics, comparison to predicate device.*

Confidant 2.0 provides equivalent functionality as the following legally marketed device:

- The Hermes System K050929 (DRG)

Two technical characteristics differentiate The Confidant 2.0 from the predicate device:

1. *Additional Support of Off The Shelf Measurement Devices* – Confidant 2.0 supports six models of off the shelf glucose meters, two models of blood pressure cuffs and two models of weight scales. The predicate device provided support for one glucose meter, one blood pressure cuff and one weight scale.

2. *Battery Powered Data Converter* – Confidant 2.0 uses a battery powered serial to Bluetooth data converter. The predicate device used an AC powered unit.

6 *Discussion of functional and safety testing.*

An extensive collection of tests has been conducted and successfully completed, including usability and pilot studies, software unit, integration, system and load/performance testing and document verification.

7 *Conclusion*

Based on extensive performance testing and a comparison to the predicate device, it is the conclusion of Confidant Inc. that Confidant 2.0 is substantially equivalent to the previously cleared predicate device and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2006

Confidant Inc.
c/o Mr. Daniel R. Plonski
Director of Product Management
2530 Meridian Parkway, Suite 300
Durham, NC 27713

Re: K062215
Trade Name: Confidant 2.0
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitters and receivers
Regulatory Class: Class II (two)
Product Code: DRG
Dated: September 15, 2006
Received: September 18, 2006

Dear Mr. Plonski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240)276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062215

Device Name: Confidant 2.0

Indications For Use: Confidant 2.0 is intended to be used by out-of-hospital patients as a means to collect and transmit medical measurements (such as blood glucose level, weight, and blood pressure) to their healthcare provider and to receive returned educational and motivational messages to help them better understand and manage their chronic condition. Confidant 2.0 is to be used only upon prescription of a licensed physician or other authorized healthcare provider.

Confidant 2.0 is an accessory device that collects data from a range of supported monitoring devices. The data is collected and sent using standard wireless technologies and maintained on an associated database server located within the healthcare facility. Based on patient specific parameters set by the healthcare provider, educational and motivational messages are returned to the patient.

Confidant 2.0 is not intended for emergency calls or for transmission or indication of any real-time alarms or time-critical data. This device is not intended as a substitute for direct medical supervision or emergency intervention.
Confidant 2.0 is not intended to provide automated treatment decisions, or to be used as a substitute for professional healthcare judgment. All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062215